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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/612,668 | 07/01/2003 | Simon Jones | 8702.0018-08000 | 3471 |

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| EXAMINER | |
|---|---|
| SZPERKA, MICHAEL EDWARD | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1644 | |

DATE MAILED: 06/28/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/612,668 | JONES ET AL. | |
| | Examiner | Art Unit | |
| | Michael Szperka | 1644 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *11 April 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *29-55* is/are pending in the application.

4a) Of the above claim(s) *48-55* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *29-47* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.



S.a.J

## DETAILED ACTION

1. Applicant's amendment and response received April 11, 2005 is acknowledged.

Claims 29-36, 40, and 44 have been amended.

Claims 48-55 stand withdrawn as per the office action mailed January 11, 2005.

Claims 29-55 are pending in the instant application.

Applicant's is thanked for the amendment to the specification to update priority information. Applicant is also thanked for the updated abstract that now makes references to the antibodies of the instant invention.

### *Claim Rejections - 35 USC § 101*

2. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

The rejection of claims 29-47 under 35 U.S.C. 101 as being drawn to non-statutory subject material has been withdrawn due to Applicant's amendment to the claims to indicate that the claimed antibodies have been purified and as such cannot be considered as a product of nature.

***Claim Rejections - 35 USC § 112***

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 44-47 stand rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claims contain subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention for the reasons of record set forth in the office action mailed January 1, 2005.

Applicant's arguments filed April 11, 2005 have been fully considered but they are not persuasive. Applicant has argued on pages 9 and 10 of the response that the rejection for lack of enablement due to issues regarding the availability of essential deposited biological material should be withdrawn in view of Applicant's submission of the deposit receipt received from ATCC. This is not sufficient to remove the rejection for the following reasons:

The filing receipt from ATCC proves that ATCC accession numbers 69948 and 69949 have been deposited with an authorized international depository. However, this receipt does not contain an affidavit or declaration by applicants or someone associated with the patent owner who is in a position to make such assurances, or a statement by an attorney of record over his or her signature, stating that ATCC 69948 and ATCC 69949 will be replaced if the cultures die or are destroyed nor does it contain a sworn

statement that ATCC 69948 and ATCC 69949 will be irrevocably and without restriction or condition released to the public upon the issuance of a patent. As stated in paragraph 5 of the office action mailed January 11, 2005:

> If the deposit has been made under the terms of the Budapest Treaty, an affidavit or declaration by applicants or someone associated with the patent owner who is in a position to make such assurances, or a statement by an attorney of record over his or her signature, stating **that ATCC 69948 and ATCC 69949 have been deposited under the Budapest Treaty and that ATCC 69948 and ATCC 69949 will be irrevocably and without restriction or condition released to the public upon the issuance of a patent** would satisfy the deposit requirement made herein. See 37 CFR 1.808. Further, the record must be clear that the deposit will be maintained in a public depository for a period of 30 years after the date of deposit or 5 years after the last request for a sample or for the enforceable life of the patent, whichever is longer. See 37 CFR 1.806 and MPEP 2410-2410.01. If the deposit has not been made under the Budapest treaty, then an affidavit or declaration by applicants or someone associated with the patent owner who is in a position to make such assurances, or a statement by an attorney of record over his or her signature must be made, stating that the deposit has been made at an acceptable depository and that the criteria set forth in 37 CFR 1.801-1.809, have been met.
>
> If the deposit was made after the effective filing date of the application for a patent in the United States, a verified statement is required from a person in a

position to corroborate that the vector described in the specification as filed are the same as that deposited in the depository. Corroboration may take the form of a showing of a chain of custody from applicant to the depository coupled with corroboration that the deposit is identical to the biological material described in the specification and in the applicant's possession at the time the application was filed.

***Claim Rejections - 35 USC § 112***

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. The rejection of claims 29-47 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention as detailed in parts A and B of paragraph 7 of the office action mailed January 11, 2005 has been withdrawn due to Applicant's amendments to the claims.

The following are new grounds of rejection.

7. Claims 40-43 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claims contain subject matter which was not described in the specification in such a way as to enable one skilled in the art to

which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claims 40-43 recite antibodies that specifically bind polypeptides that have activity in a mixed micelle assay and are encoded by polynucleotides that hybridize to the complement of specified nucleic acid sequences under specific conditions. The fact that two nucleic acid sequences will hybridize under moderate or stringent conditions does not in and of itself require that the two sequences share any functional activity. Further, it was well known in the art at the time the invention was made that hybridization could occur between two sequence based upon short stretches of 100% identity (Alberts et al. *Molecular Biology of the Cell, Third Edition*, pages 104-107, 306, and 223-228, see entire selection). Thus a great deal of sequence variability *with respect to the full-length nucleic acid that hybridizes* to the complement of a recited SEQ ID is possible since neither the length of nucleotide that hybridizes nor the length of the complement to a SEQ ID sequence are clearly recited. It is noted that the polypeptide encoded by the hybridizing polynucleotide is recited as having activity in a mixed micelle assay. However, it does not appear that the specification teaches which amino acids of calcium independent cytosolic phospholipase A2/B must be maintained in order retain enzymatic activity in the mixed micelle assay. The sizes of SEQ ID No:18, 20, and 22 are quite different (as are the sizes of the polypeptides they encode which are 292, 687 and 688 amino acids respectively due to alternate splicing), but none of these are disclosed as encoding the full-length human enzyme (see particularly page 12, lines 3-14). The polypeptide encoded by SEQ ID NO:18 appears to be

completely contained within SEQ ID NO:20 and 22, but it is not clear what mutations or alterations can be made to the amino acid sequence without disrupting functional activity. Nucleotides that would hybridize under the recited conditions would still contain mismatched nucleotide basepairs. Some of these differences will result in alterations to the amino acid sequence of the enzyme (Alberts et al., pages 104-107, 306, and 223-228, see entire selection). Since it is not known what alterations can be made to the amino acid sequence of the calcium independent cytosolic phospholipase A2/B enzyme that are consistent with maintenance of enzymatic activity, it would not be possible for a skilled artisan to make the recited polynucleotides that hybridize with the complement of the indicated SEQ ID sequences that have the desired functional properties without further experimentation. If such polypeptides cannot be made, then it would also not be possible to make antibodies that bind to such polypeptides without further experimentation.

8. Claims 44-47 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for antibodies that bind polypeptides encoded by the nucleic acids of SEQ ID NO:16, 18, 20, 22 and the polypeptides encoded by the sense strand of the nucleic acid insert in the plasmids of ATCC accession numbers 69948 and 69949, does not reasonably provide enablement for antibodies that bind the polypeptide encoded by the complement of any of the previously indicated nucleic acid sequences. The specification does not enable any person skilled in the art to which it pertains, or

with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The specification does not teach that the complementary strand of the recited SEQ ID numbers also encode calcium independent cytosolic phospholipase A2/B enzymes. It is well known in the art that complementary strand of a nucleic acid sequence encodes a polypeptide with a completely different amino acid sequence, presuming that the complementary strand contains an initiation codon and an open reading frame (Alberts et al. *Molecular Biology of the Cell, Third Edition*, pages 104-107 and 223-228, see entire selection). As such, polynucleotides that are complementary to SEQ ID NO:16, 18, 20, 22, or the sense strand of the DNA inserts in the plasmids contained in ATCC accession numbers 69948 and 69949 encode polypeptides that are not calcium independent cytosolic phospholipase A2/B enzymes. Antibodies that bind the proteins encoded by complementary polynucleotide sequences do not bind calcium independent cytosolic phospholipase A2/B enzymes and are not disclosed as being part of Applicant's invention. Therefore, it would be impossible for a skilled artisan to use the full scope of Applicant's invention as currently claimed.

The following are new grounds of rejection necessitated by Applicant's amendments to the claims received April 11, 2005.

9. Claims 29-39 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Applicant has amended the claims to recite an antibody that binds an epitope and has not indicated to the examiner where written support for this limitation "epitope" can be found. A search of the specification by the examiner failed to uncover clear support for this new limitation. Applicant is invited to point out where such support can be found in the specification. An alternate possibility would be to amend the claims such that "the antibody specifically binds an amino acid sequence selected from..." or something similar that does not rely upon the use of terms that do not appear to be supported by the specification.

10. Claims 29-47 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Applicant has amended the claims to recite a purified antibody to obviate a rejection under 35 USC 101, as was suggested by the examiner. Upon closer review of the specification, the examiner could not locate support in the specification for the

purification of the antibodies of the instant invention. Applicant is invited to indicate where such support can be found, and the examiner apologizes for the potentially flawed suggestion for how to obviate the rejection under 35 USC 101.

11. No claims are allowable.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Szperka whose telephone number is 571-272-2934. The examiner can normally be reached on M-F 9-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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June 22, 2005

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